



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Bennett *et al.*

Appl. No. 10/622,088

Filed: July 18, 2003

For: **Viral Vectors Containing
Recombination Sites**

Confirmation No. 1853

Art Unit: 1653

Examiner: *To be assigned*

Atty. Docket: 0942.5450007/RWE/BJD/SJE

Information Disclosure Statement

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450
Sir:

Listed on accompanying Form PTO-1449 are documents that may be considered material to the examination of this application, in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.56, 1.97 and 1.98.

Copies of documents AA1-AK1, AA2-AK2, AA3-AK3, AA4-AK4, AA5-AK5, AA6-AK6, AA7-AK7 and AA8-AF8 are not provided in accordance with the U.S. Patent and Trademark Office pre-OG notice of July 11, 2003, which states "[t]he Office hereby waives the requirement under 37 CFR 1.98 (a)(2)(i) for submitting a copy of each cited U.S. patent and each cited U.S. patent application publication for all U.S. national patent applications filed after June 30, 2003." A copy of each of the other documents is provided.

The Examiner's attention is directed to the following co-pending U.S. Patent Applications, which are directed to related technical subject matter:

U.S. Application No. 09/177,387, Hartley *et al.*, filed October 23, 1998, and submitted herewith as document AS76;

U.S. Application No. 09/517,466, Hartley *et al.*, filed March 2, 2000, and submitted herewith as document **AT76**;

U.S. Application No. 09/695,065, Brasch *et al.*, filed October 25, 2000, and submitted herewith as document **AR77**; and

U.S. Application No. 09/984,239, Brasch *et al.*, filed October 29, 2001, and submitted herewith as document **AS77**.

The identification of these U.S. Patent Applications is not to be construed as a waiver of secrecy as to these applications now or upon issuance of the present application as a patent. The Examiner is respectfully requested to consider the cited applications and the art cited therein during examination.

Where the publication date of a listed document does not provide a month of publication, the year of publication of the listed document is sufficiently earlier than the effective U.S. filing date and any foreign priority date so that the month of publication is not in issue. Applicants have listed publication dates on the attached Form PTO-1449 based on information presently available to the undersigned. However, the listed publication dates should not be construed as an admission that the information was actually published on the date indicated.

Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

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This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist. The Examiner is specifically requested not to rely solely on the material submitted herewith.

This Information Disclosure Statement is being filed before the mailing date of a first Office Action on the merits. No statement or fee is required.

It is respectfully requested that the Examiner initial and return a copy of the enclosed Form PTO-1449, and indicate in the official file wrapper of this patent application that the documents have been considered.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

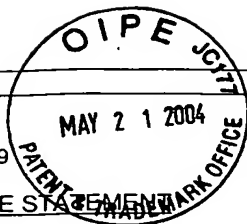
Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

A handwritten signature in black ink, appearing to read "Brian J. Del Buono", with a stylized flourish at the end.

Brian J. Del Buono
Attorney for Applicants
Registration No. 42,473

Date: May 21, 2004
1100 New York Avenue, N.W.
Washington, D.C. 20005-3934
(202) 371-2600



FORM PTO-1449

INFORMATION DISCLOSURE STATEMENT

ATTY. DOCKET NO.
0942.5450007/RWE/BJD/SJEAPPLICATION NO.
10/622,088FIRST NAMED INVENTOR
Bennett *et al.*FILING DATE
July 18, 2003ART UNIT
1653

U.S. PATENT DOCUMENTS

| EXAMINER INITIAL | | DOCUMENT NUMBER | DATE | NAME | CLASS | SUB-CLASS | FILING DATE |
|------------------|-----|-----------------|------------|--------------------------|-------|-----------|-------------|
| | AA1 | 4,859,587 | 08/22/1989 | Roizman | | | 04/25/1986 |
| | AB1 | 4,879,239 | 11/07/1989 | Daggett <i>et al.</i> | | | 09/09/1986 |
| | AC1 | 4,960,707 | 10/02/1990 | Lacks | | | 08/17/1987 |
| | AD1 | 5,077,214 | 12/31/1991 | Guarino <i>et al.</i> | | | 07/07/1989 |
| | AE1 | 5,082,784 | 01/21/1992 | Chatterjee <i>et al.</i> | | | 03/20/1990 |
| | AF1 | 5,098,839 | 03/24/1992 | Polisson | | | 05/10/1990 |
| | AG1 | 5,139,942 | 08/18/1992 | Benner | | | 05/19/1988 |
| | AH1 | 5,147,800 | 09/15/1992 | Hammond <i>et al.</i> | | | 06/08/1990 |
| | AI1 | 5,155,037 | 10/13/1992 | Summers | | | 08/04/1989 |
| | AJ1 | 5,162,222 | 11/10/1992 | Guarino <i>et al.</i> | | | 09/17/1990 |
| | AK1 | 5,169,784 | 12/08/1992 | Summers <i>et al.</i> | | | 09/17/1990 |

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|------------------|-----|-----------------|------------|---------|-------|-----------|-------------|
| | AL1 | WO 94/08598 | 04/28/1994 | WIPO | | | Yes No |
| | AM1 | WO 94/12649 | 06/09/1994 | WIPO | | | Yes No |
| | AN1 | WO 94/28938 | 12/22/1994 | WIPO | | | Yes No |
| | AO1 | WO 95/00655 | 01/05/1995 | WIPO | | | Yes No |
| | AP1 | WO 96/17053 | 06/06/1996 | WIPO | | | Yes No |

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

| | | | |
|--|----|---|--|
| | AR | 1 | Abremski, K., <i>et al.</i> , "Bacteriophage P1 Cre- <i>loxP</i> Site-specific Recombination," <i>J. Biol. Chem.</i> 261:391-396, The American Society of Biological Chemists, Inc. (1986) |
| | AS | 1 | Ambler, R.P., "The structure of β -lactamases," <i>Phil. Trans. R. Soc. Lond.</i> 289:321-331, The Royal Society (1980) |
| | AT | 1 | Andersen, A.H., <i>et al.</i> , "Studies of the Topoisomerase II-mediated Cleavage and Religation Reactions by Use of a Suicidal Double-stranded DNA Substrate," <i>J. Biol. Chem.</i> 266:9203-9210, The American Society for Biochemistry and Molecular Biology, Inc. (1991) |

EXAMINER

DATE CONSIDERED

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| FORM PTO-1449 INFORMATION DISCLOSURE STATEMENT | ATTY. DOCKET NO. 0942.5450007/RWE/BJD/SJE | APPLICATION NO. 10/622,088 |
| | FIRST NAMED INVENTOR Bennett <i>et al.</i> | |
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| EXAMINER INITIAL | | DOCUMENT NUMBER | DATE | NAME | CLASS | SUB-CLASS | FILING DATE |
|------------------|-----|-----------------|------------|--------------------------|-------|-----------|-------------|
| | AA2 | 5,179,015 | 01/12/1993 | Wilson <i>et al.</i> | | | 07/23/1990 |
| | AB2 | 5,192,675 | 03/09/1993 | Chatterjee <i>et al.</i> | | | 01/17/1992 |
| | AC2 | 5,200,333 | 04/06/1993 | Wilson | | | 03/19/1991 |
| | AD2 | 5,202,248 | 04/13/1993 | VanCott | | | 11/02/1990 |
| | AE2 | 5,231,021 | 07/27/1993 | Chatterjee | | | 04/10/1992 |
| | AF2 | 5,244,805 | 09/14/1993 | Miller | | | 01/17/1991 |
| | AG2 | 5,248,605 | 09/28/1993 | Chatterjee | | | 12/07/1992 |
| | AH2 | 5,252,479 | 10/12/1993 | Srivastava | | | 11/08/1991 |
| | AI2 | 5,304,480 | 04/19/1994 | Chatterjee | | | 03/19/1993 |
| | AJ2 | 5,312,746 | 05/17/1994 | Longo <i>et al.</i> | | | 01/08/1993 |
| | AK2 | 5,334,526 | 08/02/1994 | Smith <i>et al.</i> | | | 05/28/1993 |

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| EXAMINER INITIAL | | DOCUMENT NUMBER | DATE | COUNTRY | CLASS | SUB-CLASS | TRANSLATION |
|------------------|-----|-----------------|------------|---------|-------|-----------|-------------|
| | AL2 | WO 96/19497 | 06/27/1996 | WIPO | | | Yes No |
| | AM2 | WO 98/56943 | 12/17/1998 | WIPO | | | Yes No |
| | AN2 | WO 01/11058 | 02/15/2001 | WIPO | | | Yes No |
| | AO | | | | | | Yes No |
| | AP | | | | | | Yes No |

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

| | | | |
|--|----|---|--|
| | AR | 2 | Andersson, S., <i>et al.</i> , Cloning, Structure, and Expression of the Mitochondrial Cytochrome P-450 Sterol 26-Hydroxylase, a Bile Acid Biosynthetic Enzyme," <i>J. Biol. Chem.</i> 264:8222-8229, The American Society for Biochemistry and Molecular Biology, Inc. (1989) |
| | AS | 2 | Aoki, K., <i>et al.</i> , "Efficient Generation of Recombinant Adenoviral Vectors by Cre-lox Recombination In Vitro," <i>Mol. Med.</i> 5:224-231, Picower Institute Press (1999) |
| | AT | 2 | Araki, H., <i>et al.</i> , "Site-specific Recombinase, R, Encoded by Yeast Plasmid pSR1," <i>J. Mol. Biol.</i> 225:25-37, Academic Press (1992) |

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| | AA3 | 5,334,575 | 08/02/1994 | Noonan <i>et al.</i> | | | 12/17/1992 |
| | AB3 | 5,348,886 | 09/20/1994 | Lee <i>et al.</i> | | | 09/04/1992 |
| | AC3 | 5,470,740 | 11/28/1995 | Longo <i>et al.</i> | | | 11/04/1993 |
| | AD3 | 5,534,428 | 07/09/1996 | Longo <i>et al.</i> | | | 09/06/1994 |
| | AE3 | 5,672,344 | 09/30/1997 | Kelley <i>et al.</i> | | | 02/10/1994 |
| | AF3 | 5,686,279 | 11/11/1997 | Finer <i>et al.</i> | | | 06/10/1994 |
| | AG3 | 5,741,486 | 04/21/1998 | Pathak <i>et al.</i> | | | 06/06/1995 |
| | AH3 | 5,741,657 | 04/21/1998 | Tsien <i>et al.</i> | | | 03/20/1995 |
| | AI3 | 5,766,891 | 06/16/1998 | Shuman | | | 12/19/1994 |
| | AJ3 | 5,834,256 | 11/10/1998 | Finer <i>et al.</i> | | | 06/11/1993 |
| | AK3 | 5,851,808 | 12/22/1998 | Elledge <i>et al.</i> | | | 02/28/1997 |

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|---------------------|----|-----------------|------|---------|-------|-----------|-------------|
| | AL | | | | | | Yes No |
| | AM | | | | | | Yes No |
| | AN | | | | | | Yes No |
| | AO | | | | | | Yes No |
| | AP | | | | | | Yes No |

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

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|--|----|----------|---|
| | AR | <u>3</u> | Argos, P., <i>et al.</i> , "The integrase family of site-specific recombinases: regional similarities and global diversity," <i>EMBO J.</i> 5:433-440, IRL Press Limited (1986) |
| | AS | <u>3</u> | Baek, S-C., <i>et al.</i> , "Sustainable Systemic Delivery via a Single Injection of Lentivirus into Human Skin Tissue," <i>Hum. Gene Ther.</i> 12:1551-1558, Mary Ann Liebert, Inc. (2001) |
| | AT | <u>3</u> | Bass, B.L., "Double-Stranded RNA as a Template for Gene Silencing," <i>Cell</i> 101:235-238, Cell Press (2000) |

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| | AA4 | 5,858,740 | 01/12/1999 | Finer <i>et al.</i> | | | 05/10/1995 |
| | AB4 | 5,888,732 | 03/30/1999 | Hartley <i>et al.</i> | | | 06/07/1996 |
| | AC4 | 5,888,795 | 03/30/1999 | Hamilton | | | 09/09/1997 |
| | AD4 | 5,955,604 | 09/21/1999 | Tsien <i>et al.</i> | | | 10/21/1997 |
| | AE4 | 5,981,275 | 11/09/1999 | Armentano <i>et al.</i> | | | 04/14/1997 |
| | AF4 | 5,994,106 | 11/30/1999 | Kovesdi <i>et al.</i> | | | 11/26/1996 |
| | AG4 | 5,994,136 | 11/30/1999 | Naldini <i>et al.</i> | | | 12/12/1997 |
| | AH4 | 5,998,205 | 12/07/1999 | Hallenbeck <i>et al.</i> | | | 08/01/1997 |
| | AI4 | 5,998,208 | 12/07/1999 | Fraefel <i>et al.</i> | | | 01/21/1998 |
| | AJ4 | 6,013,516 | 01/11/2000 | Verma <i>et al.</i> | | | 10/06/1995 |
| | AK4 | 6,025,192 | 02/15/2000 | Beach <i>et al.</i> | | | 09/20/1996 |

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| | AL | | | | | | Yes No |
| | AM | | | | | | Yes No |
| | AN | | | | | | Yes No |
| | AO | | | | | | Yes No |
| | AP | | | | | | Yes No |

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

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| | AR | <u>4</u> | Bergelson, J.M., <i>et al.</i> , "Isolation of a Common Receptor for Coxsackie B Viruses and Adenoviruses 2 and 5," <i>Science</i> 275:1320-1323, The American Association for the Advancement of Science (1997) |
| | AS | <u>4</u> | Berger, J.M., "Structure of DNA topoisomerases," <i>Biochim. Biophys. Acta</i> 1400:3-18, Elsevier Science B.V. (1998) |
| | AT | <u>4</u> | Bernstein, E., <i>et al.</i> , "The rest is silence," <i>RNA</i> 7:1509-21, Cambridge University Press (2001) |

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| | AA5 | 6,031,094 | 02/29/2000 | Tsien <i>et al.</i> | | | 07/23/1998 |
| | AB5 | 6,040,174 | 03/21/2000 | Imler <i>et al.</i> | | | 05/27/1994 |
| | AC5 | 6,051,427 | 04/18/2000 | Finer <i>et al.</i> | | | 08/21/1995 |
| | AD5 | 6,086,902 | 07/11/2000 | Zamb <i>et al.</i> | | | 09/09/1994 |
| | AE5 | 6,110,735 | 08/29/2000 | Chartier <i>et al.</i> | | | 12/01/1995 |
| | AF5 | 6,120,764 | 09/19/2000 | Graham <i>et al.</i> | | | 06/07/1995 |
| | AG5 | 6,121,043 | 09/19/2000 | Cochran <i>et al.</i> | | | 08/15/1997 |
| | AH5 | 6,127,175 | 10/03/2000 | Vigne <i>et al.</i> | | | 01/19/1996 |
| | AI5 | 6,133,028 | 10/17/2000 | Imler <i>et al.</i> | | | 09/30/1999 |
| | AJ5 | 6,136,594 | 10/24/2000 | Dalemans <i>et al.</i> | | | 05/16/1995 |
| | AK5 | 6,140,087 | 10/31/2000 | Graham <i>et al.</i> | | | 05/31/1994 |

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|------------------|----|-----------------|------|---------|-------|-----------|-------------|
| | AL | | | | | | Yes No |
| | AM | | | | | | Yes No |
| | AN | | | | | | Yes No |
| | AO | | | | | | Yes No |
| | AP | | | | | | Yes No |

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

| | | | |
|--|----|----------|---|
| | AR | <u>5</u> | Bett, A.J., <i>et al.</i> , "An efficient and flexible system for construction of adenovirus vectors with insertions or deletions in early regions 1 and 3," <i>Proc. Natl. Acad. Sci.</i> 91:8802-8806, The National Academy of Sciences (1994) |
| | AS | <u>5</u> | Blissard, G.W., and Rohrmann, G.F., "Baculovirus gp64 Gene Expression: Analysis of Sequences Modulating Early Transcription and Transactivation by IE1," <i>J. Virology</i> 65:5820-5827, American Society for Microbiology (1991) |
| | AT | <u>5</u> | Blissard, G.W., and Rohrmann, G.F., "Location, Sequence, Transcriptional Mapping, and Temporal Expression of the gp64 Envelope Glycoprotein Gene of the <i>Orgyia pseudotsugata</i> Multicapsid Nuclear Polyhedrosis Virus," <i>Virology</i> 170:537-555, Academic Press, Inc. (1989) |

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1653**U.S. PATENT DOCUMENTS**

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| | AA6 | 6,143,557 | 11/07/2000 | Hartley <i>et al.</i> | | | 01/20/1999 |
| | AB6 | 6,156,497 | 12/05/2000 | Kaleko | | | 04/13/1998 |
| | AC6 | 6,165,782 | 12/26/2000 | Naldini <i>et al.</i> | | | 03/18/1999 |
| | AD6 | 6,171,861 | 01/09/2001 | Hartley <i>et al.</i> | | | 01/12/1998 |
| | AE6 | 6,194,191 | 02/27/2001 | Zhang <i>et al.</i> | | | 11/20/1997 |
| | AF6 | 6,204,060 | 03/20/2001 | Mehtali <i>et al.</i> | | | 07/24/1996 |
| | AG6 | 6,218,187 | 04/17/2001 | Finer <i>et al.</i> | | | 03/11/1999 |
| | AH6 | 6,228,646 | 05/08/2001 | Hardy | | | 03/07/1997 |
| | AI6 | 6,255,060 | 07/03/2001 | Eberwine <i>et al.</i> | | | 06/22/1999 |
| | AJ6 | 6,261,807 | 07/17/2001 | Crouzet <i>et al.</i> | | | 08/08/1997 |
| | AK6 | 6,270,969 | 08/07/2001 | Hartley <i>et al.</i> | | | 01/20/1999 |

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| | AL | | | | | | Yes No |
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| | AN | | | | | | Yes No |
| | AO | | | | | | Yes No |
| | AP | | | | | | Yes No |

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| | AR | <u>6</u> | Blissard, G.W., <i>et al.</i> , "A Synthetic Early Promoter from a Baculovirus: Roles of the TATA Box and Conserved Start Site CAGT Sequence in Basal Levels of Transcription," <i>Virology</i> 190:783-793, Academic Press, Inc. (1992) |
| | AS | <u>6</u> | Boshart, M., <i>et al.</i> , "A Very Strong Enhancer Is Located Upstream of an Immediate Early Gene of Human Cytomegalovirus," <i>Cell</i> 41:521-530, MIT (1985) |
| | AT | <u>6</u> | Bout, A., <i>et al.</i> , "Lung Gene Therapy: <i>In Vivo</i> Adenovirus-Mediated Gene transfer to Rhesus Monkey Airway Epithelium," <i>Human Gene Therapy</i> 5:3-10, Mary Ann Liebert, Inc. (1994) |

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| | AC7 | 6,281,000 | 08/28/2001 | Chartier <i>et al.</i> | | | 12/21/1999 |
| | AD7 | 6,291,162 | 09/18/2001 | Tsien <i>et al.</i> | | | 10/15/1996 |
| | AE7 | 6,300,118 | 10/09/2001 | Chavez <i>et al.</i> | | | 06/07/1995 |
| | AF7 | 6,319,703 | 11/20/2001 | Speck | | | 04/25/1997 |
| | AG7 | 6,323,024 | 11/27/2001 | Tracy <i>et al.</i> | | | 03/27/2000 |
| | AH7 | 2002/0007051 A1 | 01/17/2002 | Cheo <i>et al.</i> | | | 12/11/2000 |
| | AI7 | 6,342,224 | 01/29/2002 | Bruck <i>et al.</i> | | | 02/18/2000 |
| | AJ7 | 6,342,229 | 01/29/2002 | O'Hare <i>et al.</i> | | | 08/02/1999 |
| | AK7 | 6,379,967 | 04/30/2002 | Meredith <i>et al.</i> | | | 03/04/1999 |

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| | AL | | | | | | Yes No |
| | AM | | | | | | Yes No |
| | AN | | | | | | Yes No |
| | AO | | | | | | Yes No |
| | AP | | | | | | Yes No |

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

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FORM PTO-1449

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10/622,088FIRST NAMED INVENTOR
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| | AR | <u>19</u> | Fallaux, F.J., <i>et al.</i> , "Characterization of 911: A New Helper Cell Line for the Titration and Propagation of Early Region 1-Deleted Adenoviral Vectors," <i>Hum. Gene Ther.</i> 7:215-222, Mary Ann Liebert, Inc. (1996) |
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| | AT | <u>19</u> | Fan, X., <i>et al.</i> , "Efficient Adenoviral Vector Transduction of Human Hematopoietic SCID-Repopulating and Long-Term Culture-Initiating Cells," <i>Hum. Gene Ther.</i> 11:1313-1327, Mary Ann Liebert, Inc. (2000) |

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| | AT | <u>21</u> | Gill, D.R., <i>et al.</i> , "Increased persistence of lung gene expression using plasmids containing the ubiquitin C or elongation factor 1 α promoter," <i>Gene Ther.</i> 8:1539-1546, Nature Publishing Group (2001) |

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| | AR | <u>22</u> | Godeau, F., <i>et al.</i> , "Replication inhibition by nucleoside analogues of a recombinant <i>Autographa californica</i> multicapsid nuclear polyhedrosis virus harboring the herpes thymidine kinase gene driven by the IE-1(0) promoter: a new way to select recombinant baculoviruses," <i>Nucl. Acids Res.</i> 20:6239-6246, Oxford University Press (1992) |
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| | AS | <u>24</u> | Guy, J., <i>et al.</i> , "Delivery of DNA into Mammalian Cells by Receptor-Mediated Endocytosis and Gene Therapy," <i>Mol. Biotechnol.</i> 3:237-248, Humana Press, Inc. (1995) |
| | AT | <u>24</u> | Hanai, R., <i>et al.</i> , "Human TOP3: A single-copy gene encoding DNA topoisomerase III," <i>Proc. Natl. Acad. Sci.</i> 93:3653-3657, The National Academy of Sciences (1996) |

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| | AR | <u>25</u> | Harrison, T., <i>et al.</i> , "Host-Range Mutants of Adenovirus Type 5 Defective for Growth in HeLa Cells," <i>Virology</i> 77:319-329, Academic Press, Inc. (1977) |
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| | AR | <u>26</u> | Hearing, P., <i>et al.</i> , "Identification of a Repeated Sequence Element Required for Efficient Encapsidation of the Adenovirus Type 5 Chromosome," <i>J. Virol.</i> 61:2555-2558, American Society for Microbiology (1987) |
| | AS | <u>26</u> | Hegedus, D.D., <i>et al.</i> , "A series of broad host range shuttle vectors for constitutive and inducible expression of heterologous proteins in insect cell lines," <i>Gene</i> 207:241-249, Elsevier Science B.V. (1998) |
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| | Bennett <i>et al.</i> | |
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| | FIRST NAMED INVENTOR Bennett <i>et al.</i> | | | |
| | FILING DATE July 18, 2003 | | ART UNIT 1653 | |
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| | AT | <u>44</u> | Moss, B., and Earl, P.L., "Overview of the Vaccinia Virus Expression System," in <i>Current Protocols in Molecular Biology</i> , Ausubel, F.M., <i>et al.</i> , eds., John Wiley & Sons, New York, NY, pp. 16.15-16.18 (1998) |

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| | AT | <u>45</u> | Mulligan, R.C., "The Basic Science of Gene Therapy," <i>Science</i> 260:926-932, American Association for the Advancement of Science (1993) |

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| | FIRST NAMED INVENTOR Bennett <i>et al.</i> | | | |
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| | FIRST NAMED INVENTOR Bennett <i>et al.</i> | |
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| | AS | <u>70</u> | Zhang, W-W., <i>et al.</i> , "Detection of Wild-Type Contamination in a Recombinant Adenoviral Preparation by PCR," <i>BioTechniques</i> 18:444-447, Eaton Publishing Co. (1995) |
| | AT | <u>70</u> | Zufferey, R., <i>et al.</i> , "Self-Inactivating Lentivirus Vector for Safe and Efficient In Vivo Gene Delivery," <i>J. Virol.</i> 72:9873-9880, American Society for Microbiology (1998) |

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FORM PTO-1449

INFORMATION DISCLOSURE STATEMENTATTY. DOCKET NO.
0942.5450007/RWE/BJD/SJEAPPLICATION NO.
10/622,088FIRST NAMED INVENTOR
Bennett *et al.*FILING DATE
July 18, 2003ART UNIT
1653**U.S. PATENT DOCUMENTS**

| EXAMINER INITIAL | | DOCUMENT NUMBER | DATE | NAME | CLASS | SUB-CLASS | FILING DATE |
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| | AL | | | | | | Yes No |
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| | AP | | | | | | Yes No |

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

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| | AR | <u>71</u> | Zylka, M.J., and Schnapp, B.J., "Optimized Filter Set and Viewing Conditions for the S65T Mutant of GFP in Living Cells," <i>BioTechniques</i> 21:220-226, Eaton Publishing Co. (1996) |
| | AS | <u>71</u> | NCBI Entrez, Genbank Report, Accession No. BC000141, Strausberg, R.L., <i>et al.</i> , (2002) |
| | AT | <u>71</u> | NCBI Entrez, Genbank Report, Accession No. X02340 M10241, Hollingshead, S., and Vapnek, D., (1985) |

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OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

| | | | |
|--|----|-----------|--|
| | AR | <u>72</u> | 293A Cell Line Manual, catalog no. R705-07, version B, March 31, 2003, Invitrogen Corporation, Carlsbad, CA |
| | AS | <u>72</u> | Bac to Bac™ Baculovirus Expression System Manual, catalog nos. 10359-016, 10360-014, 10584-027, 10712-024, version C, p. 27, December 19, 2002, Invitrogen Corporation, Carlsbad, CA |
| | AT | <u>72</u> | Bac to Bac™ Baculovirus Expression System Manual, catalog nos. 11827-011, 11806-015, 11804-010 and 11807-013, version D, October 3, 2003, Invitrogen Corporation, Carlsbad, CA |

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OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

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| | AR | <u>73</u> | Bac-n-blue™ Manual, catalog no. K855-01, version M, December 10, 2002, Invitrogen Corporation, Carlsbad, CA |
| | AS | <u>73</u> | Guide To Baculovirus Expression Systems (BEVS) and Insect Cell Culture Techniques Manual, catalog nos. 10359016, 10360014, 10608016, 11827011, February 27, 2002, Invitrogen Corporation, Carlsbad, CA |
| | AT | <u>73</u> | pAd/CMV/V5-DEST™ and pAd/PL-DEST™ GATEWAY™ Vector Manual, catalog nos. V493-20 and 494-20, version C, September 22, 2003, Invitrogen Corporation, Carlsbad, CA |

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| | AS | <u>74</u> | pLenti6/V5 Directional TOPO® Cloning Kit Manual, catalog no. K4955-10, version B, Invitrogen Corporation, Carlsbad, CA |
| | AT | <u>74</u> | pLenti4/V5-DEST™ GATEWAY™ Vector Pack manual, catalog nos. V496-10, V498-10, and V499-10, version C, February 18, 2003, Invitrogen Corporation, Carlsbad, CA |

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| | AS | <u>75</u> | The GATEWAY™ Technology Instruction Manual, catalog nos. 12535-019, and 12535-027, version E, September 22, 2003, Invitrogen Corporation, Carlsbad, CA |
| | AT | <u>75</u> | ViraPower™ Adenoviral Expression System Manual, catalog nos. K4930-00, and K4940-00, version A, July 15, 2002, Invitrogen Corporation, Carlsbad, CA |

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| | AR | <u>76</u> | ViraPower™ Lentiviral Expression System Manual, catalog nos. K4950-00, K4960-00, K4970-00, K4975-00, K4980-00, K4985-00, and K4990-00, version D, April 2, 2002, Invitrogen Corporation, Carlsbad, CA |
| | AS | <u>76</u> | United States Application No. 09/177,387, Hartley <i>et al.</i> , filed October 23, 1998 (NOT PUBLISHED) |
| | AT | <u>76</u> | United States Application No. 09/517,466, Hartley <i>et al.</i> , filed March 2, 2000 (NOT PUBLISHED) |

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OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

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| | AR | <u>77</u> | United States Application No. 09/695,065, Brasch <i>et al.</i> , filed October 25, 2000 (NOT PUBLISHED) |
| | AS | <u>77</u> | United States Application No. 09/984,239, Brasch <i>et al.</i> , filed October 29, 2001 (NOT PUBLISHED) |
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Bennett *et al.*

Appl. No. 10/622,088

Filed: July 18, 2003

For: **Viral Vectors Containing
Recombination Sites**



Confirmation No. 1853

Art Unit: 1653

Examiner: *To be assigned*

Atty. Docket: 0942.5450007/RWE/BJD/SJE

First Supplemental Information Disclosure Statement

Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450
Sir:

Listed on accompanying Form PTO-1449 are documents that may be considered material to the examination of this application, in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.56, 1.97 and 1.98.

The numbering on this First Supplemental Information Disclosure Statement is a continuation of the numbering in Applicants' Information Disclosure Statement filed herewith, in connection with the above-captioned application.

Copies of documents **AG8-AK8**, **AA9-AK9**, **AA10-AK10**, **AA11-AK11**, **AA12-AK12**, **AA13-AK13**, **AA14-AK14** and **AA15-AK15** are not provided in accordance with the U.S. Patent and Trademark Office pre-OG notice of July 11, 2003, which states "[t]he Office hereby waives the requirement under 37 CFR 1.98 (a)(2)(i) for submitting a copy of each cited U.S. patent and each U.S. patent application publication for all U.S. national patent applications filed after June 30, 2003."

In accordance with 37 C.F.R. § 1.98(a)(3), Applicants' undersigned representative submits the following, in regards to non-English language documents **AN8** and **AL9** cited on Form PTO-1449:

Document **AN8**, PCT Patent Publication No. WO 98/53056, is in the German language.
An unverified English language document related to **AN8** is attached as document **AJ13**.

Document **AL9**, PCT Patent Publication No. WO 99/25851, is in the Japanese language.
An unverified English language document related to **AL9** is attached as document **AO9**.

The Examiner's attention is directed to the following patents and co-pending U.S. Patent Applications, which are directed to related technical subject matter:

U.S. Patent Application No. 10/640,422, Cheo *et al.*, filed August 14, 2003 and submitted herewith as document **AS180**;

U.S. Application No. 09/498,074, Hartley *et al.*, now U.S. Patent No. 6,720,140, issued April 13, 2004, listed herein as document **AJ15**; and

U.S. Patent Application No. 10/680,316, Hartley *et al.*, filed October 8, 2003 published April 1, 2004 as 2004/0063207A1 and submitted herewith as document **AK15**.

The identification of these U.S. Patent Applications is not to be construed as a waiver of secrecy as to these applications now or upon issuance of the present application as a patent. The Examiner is respectfully requested to consider the cited applications and the art cited therein during examination.

Where the publication date of a listed document does not provide a month of publication, the year of publication of the listed document is sufficiently earlier than the effective U.S. filing date and any foreign priority date so that the month of publication is not in issue. Applicants have listed publication dates on the attached Form PTO-1449 based on information presently available to the undersigned. However, the listed publication dates should not be construed as an admission that the information was actually published on the date indicated.

Bennett *et al.*
Appl. No. 10/622,088

Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist. The Examiner is specifically requested not to rely solely on the material submitted herewith.

This Information Disclosure Statement is being filed before the mailing date of a first Office Action on the merits. No statement or fee is required.

It is respectfully requested that the Examiner initial and return a copy of the enclosed Form PTO-1449, and indicate in the official file wrapper of this patent application that the documents have been considered.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.



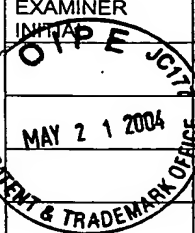
Brian J. Del Buono
Attorney for Applicants
Registration No. 42,473

Date: May 21, 2004
1100 New York Avenue, N.W.
Washington, D.C. 20005-3934
(202) 371-2600

FORM PTO-1449

FIRST SUPPLEMENTAL
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| | AH8 | 4,673,640 | 06/16/1987 | Backman | | | 04/30/1984 |
| | AI8 | 4,683,195 | 07/28/1987 | Mullis <i>et al.</i> | | | 02/07/1986 |
| | AJ8 | 4,683,202 | 07/28/1987 | Mullis | | | 10/25/1985 |
| | AK8 | 4,743,546 | 05/10/1998 | Backman <i>et al.</i> | | | 02/13/1985 |

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|---------------------|-----|-----------------|------------|---------|-------|-----------|-------------|
| | AL | | | | | | Yes No |
| | AM | | | | | | Yes No |
| | AN | | | | | | Yes No |
| | AO2 | EP 0 160 571 A2 | 11/06/1985 | Europe | | | Yes No |
| | AP2 | EP 0 220 009 | 04/29/1987 | Europe | | | Yes No |

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| | AR | <u>78</u> | Abremski, K., and Hoess, R., "Bacteriophage P1 Site-specific Recombination - Purification and Properties of the Cre Recombinase Protein," <i>J. Biol. Chem.</i> 259:1509-1514, American Society for Biochemistry and Molecular Biology, Inc., Baltimore, MD (1984) |
| | AS | <u>78</u> | Abremski, K., <i>et al.</i> , "Studies on the Properties of P1 Site-Specific Recombination: Evidence for Topologically Unlinked Products Following Recombination," <i>Cell</i> 32:1301-1311, Cell Press (1993) |
| | AT | <u>78</u> | Abremski, K., and Gottesman, S., "Purification of the Bacteriophage λ <i>xis</i> Gene Product Required for λ Excisive Recombination," <i>J. Biol. Chem.</i> 257(16):9658-9662, American Society for Biochemistry and Molecular Biology (1982) |

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| | AA9 | 4,959,317 | 09/25/1990 | Sauer | | | 04/29/1987 |
| | AB9 | 4,965,188 | 10/23/1990 | Mullis <i>et al.</i> | | | 06/17/1987 |
| | AC9 | 5,093,257 | 03/03/1992 | Gray | | | 11/01/1989 |
| | AD9 | 5,102,797 | 04/07/1992 | Tucker <i>et al.</i> | | | 05/26/1989 |
| | AE9 | 5,159,062 | 10/27/1992 | Knapp <i>et al.</i> | | | 01/19/1990 |
| | AF9 | 5,227,288 | 07/13/1993 | Blattner | | | 10/01/1990 |
| | AG9 | 5,286,632 | 02/15/1994 | Jones | | | 01/09/1991 |
| | AH9 | 5,334,375 | 08/02/1994 | Nabi <i>et al.</i> | | | 07/16/1992 |
| | AI9 | 5,354,668 | 10/11/1994 | Auerbach | | | 10/15/1993 |
| | AJ9 | 5,378,618 | 01/03/1995 | Sternberg <i>et al.</i> | | | 09/29/1992 |
| | AK9 | 5,434,066 | 07/18/1995 | Bebbee <i>et al.</i> | | | 03/15/1994 |

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|---------------------|-----|-----------------|------------|---------|-------|-----------|-------------|
| | AL3 | EP 0 300 422 | 01/25/1989 | Europe | | | Yes No |
| | AM3 | WO 90/11375 | 10/04/1990 | WIPO | | | Yes No |
| | AN3 | WO 91/02801 | 03/07/1991 | WIPO | | | Yes No |
| | AO3 | EP 0 427 074 | 05/15/1991 | Europe | | | Yes No |
| | AP3 | WO 91/09957 | 07/11/1991 | WIPO | | | Yes No |

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| | AR | <u>79</u> | Adams, D.E., <i>et al.</i> , "Cre-lox Recombination in <i>Escherichia coli</i> Cells: Mechanistic Differences from the <i>in Vitro</i> Reaction," <i>J. Mol. Biol.</i> 226:661-673, Academic Press (1992) |
| | AS | <u>79</u> | Akagi, K., <i>et al.</i> , "Cre-mediated somatic site-specific recombination in mice," <i>Nucl. Acids Res.</i> 25:1781-1788, Oxford University Press (May 1997) |
| | AT | <u>79</u> | Aladjem, M.I., <i>et al.</i> , "Positive Selection of FLP-Mediated Unequal Sister Chromatid Exchange Products in Mammalian Cells," <i>Mol. Cell. Biol.</i> 17:857-861, American Society for Microbiology (February 1997) |

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| | AA10 | 5,470,727 | 11/28/1995 | Mascarenhas <i>et al.</i> | | | 12/21/1993 |
| | AB10 | 5,527,695 | 06/18/1996 | Hodges <i>et al.</i> | | | 01/29/1993 |
| | AC10 | 5,591,609 | 01/07/1997 | Auerbach | | | 02/03/1995 |
| | AD10 | 5,605,793 | 02/25/1997 | Stemmer | | | 02/17/1994 |
| | AE10 | 5,614,389 | 03/25/1997 | Auerbach | | | 09/26/1995 |
| | AF10 | 5,635,381 | 06/03/1997 | Hooykaas <i>et al.</i> | | | 01/20/1995 |
| | AG10 | 5,650,308 | 07/22/1997 | Baum | | | 06/07/1995 |
| | AH10 | 5,650,557 | 07/22/1997 | Hannah <i>et al.</i> | | | 06/07/1995 |
| | AI10 | 5,658,772 | 08/19/1997 | Odell <i>et al.</i> | | | 07/27/1994 |
| | AJ10 | 5,677,170 | 10/14/1997 | Devine <i>et al.</i> | | | 03/02/1994 |
| | AK10 | 5,677,177 | 10/14/1997 | Wahl <i>et al.</i> | | | 06/07/1995 |

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| | AL4 | WO 91/16427 | 10/31/1991 | WIPO | | | Yes No |
| | AM4 | WO 92/15694 | 09/17/1992 | WIPO | | | Yes No |
| | AN4 | WO 92/20791 | 11/26/1992 | WIPO | | | Yes No |
| | AO4 | WO 92/22650 | 12/23/1992 | WIPO | | | Yes No |
| | AP4 | EP 0 542 466 A2 | 05/19/1993 | Europe | | | Yes No |

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| | AR | <u>80</u> | Albert, H., <i>et al.</i> , "Site-specific Integration of DNA into wild-type and mutant <i>lox</i> sites placed in the plant genome," <i>Plant J.</i> 7:649-659, Blackwell Science Ltd. (1995) |
| | AS | <u>80</u> | Andrews, B.J., <i>et al.</i> , "The FLP Recombinase of the 2 μ Circle DNA of Yeast: Interaction with Its Target Sequences," <i>Cell</i> 40:795-803, Cell Press (1985) |
| | AT | <u>80</u> | Andrews, B.J., <i>et al.</i> , "Interaction of the FLP Recombinase of the <i>Saccharomyces cerevisiae</i> 2 μ m Plasmid with Mutated Target Sequences," <i>Mol. Cell. Biol.</i> 6:2482-2489, American Society for Microbiology (1986) |

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| | AA11 | 5,710,248 | 01/20/1998 | Grose | | | 07/29/1996 |
| | AB11 | 5,723,765 | 03/03/1998 | Oliver <i>et al.</i> | | | 06/07/1995 |
| | AC11 | 5,728,551 | 03/17/1998 | Devine <i>et al.</i> | | | 03/02/1995 |
| | AD11 | 5,733,733 | 03/31/1998 | Auerbach | | | 02/01/1996 |
| | AE11 | 5,733,743 | 03/31/1998 | Johnson <i>et al.</i> | | | 06/10/1996 |
| | AF11 | 5,744,336 | 04/28/1998 | Hodges <i>et al.</i> | | | 03/08/1996 |
| | AG11 | 5,776,449 | 07/07/1998 | Baum <i>et al.</i> | | | 09/20/1996 |
| | AH11 | 5,801,030 | 09/01/1998 | McVey <i>et al.</i> | | | 09/01/1995 |
| | AI11 | 5,814,300 | 09/29/1998 | Scott <i>et al.</i> | | | 03/03/1995 |
| | AJ11 | 5,830,707 | 11/03/1998 | Bushman | | | 06/05/1995 |
| | AK11 | 5,837,242 | 11/17/1998 | Holliger <i>et al.</i> | | | 05/14/1996 |

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|------------------|-----|-----------------|------------|---------|-------|-----------|-------------|
| | AL5 | WO 93/15191 | 08/05/1993 | WIPO | | | Yes No |
| | AM5 | WO 93/19172 | 09/30/1993 | WIPO | | | Yes No |
| | AN5 | CA 2,141,412 | 02/17/1994 | Canada | | | Yes No |
| | AO5 | WO 94/03624 A1 | 02/17/1994 | WIPO | | | Yes No |
| | AP5 | WO 94/09127 | 04/28/1994 | WIPO | | | Yes No |

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| | AR | <u>81</u> | Angelastro, J.M., <i>et al.</i> , "Identification of diverse nerve growth factor-regulated genes by serial analysis of gene expression (SAGE) profiling," <i>Proc. Natl. Acad. Sci. USA</i> 97:10424-10429, National Academy of Sciences (September 2000) |
| | AS | <u>81</u> | Angrand, P.O., <i>et al.</i> , "Inducible expression based on regulated recombination: a single vector strategy for stable expression in cultured cells," <i>Nucl. Acids Res.</i> 26:3263-3269, Oxford University Press (July 1998) |
| | AT | <u>81</u> | Anton, M., and Graham, F.L., "Site-Specific Recombination Mediated by an Adenovirus Vector Expressing the Cre Recombinase Protein: a Molecular Switch for Control of Gene Expression," <i>J. Virol.</i> 69:4600-4606, American Society for Microbiology (1995) |

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| | AA12 | 5,837,458 | 11/17/1998 | Minshull <i>et al.</i> | | | 05/20/1996 |
| | AB12 | 5,843,772 | 12/01/1998 | Devine <i>et al.</i> | | | 11/18/1994 |
| | AC12 | 5,858,657 | 01/12/1999 | Winter <i>et al.</i> | | | 06/07/1995 |
| | AD12 | 5,871,907 | 02/16/1999 | Winter <i>et al.</i> | | | 03/31/1994 |
| | AE12 | 5,874,259 | 02/23/1999 | Szybalski | | | 11/21/1997 |
| | AF12 | 5,916,804 | 06/29/1999 | Bushman | | | 04/17/1998 |
| | AG12 | 5,919,676 | 07/06/1999 | Graham <i>et al.</i> | | | 06/07/1995 |
| | AH12 | 5,928,914 | 07/27/1999 | Leboulch <i>et al.</i> | | | 11/05/1996 |
| | AI12 | 5,929,307 | 07/27/1999 | Hodges <i>et al.</i> | | | 12/20/1996 |
| | AJ12 | 5,962,255 | 10/05/1999 | Griffiths <i>et al.</i> | | | 12/05/1994 |
| | AK12 | 5,981,177 | 11/09/1999 | Demirjian <i>et al.</i> | | | 01/25/1995 |

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| | AL6 | WO 94/17176 | 08/04/1994 | WIPO | | | Yes No |
| | AM6 | WO 94/18333 | 08/18/1994 | WIPO | | | Yes No |
| | AN6 | WO 95/00555 | 01/05/1995 | WIPO | | | Yes No |
| | AO6 | WO 96/04393 | 02/19/1996 | WIPO | | | Yes No |
| | AP6 | WO 96/30498 | 10/03/1996 | WIPO | | | Yes No |

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| | AR | <u>82</u> | Astumian, J.H., <i>et al.</i> , "Site-specific recombination between cloned attP and attB sites from the Haemophilus influenza bacteriophage HP1 propagated in recombination deficient <i>Escherichia coli</i> ," <i>J. Bacteriol.</i> 171:1747-1750, American Society for Microbiology (1989) |
| | AS | <u>82</u> | Atlung, T., <i>et al.</i> , "A versatile method for integration of genes and gene fusions into the λ attachment site of <i>Escherichia coli</i> ," <i>Gene</i> 107:11-17, Elsevier Science (1991) |
| | AT | <u>82</u> | Ausubel, F.M., <i>et al.</i> , "Maps of Plasmids pBR322 and pUC19," in <i>Current Protocols in Molecular Biology</i> , John Wiley & Sons, Inc., Boston, MA, pp. 1.5.3-1.5.4 (1995) |

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| | AA13 | 5,989,872 | 11/22/1999 | Luo <i>et al.</i> | | | 08/12/1997 |
| | AB13 | 6,010,884 | 01/04/2000 | Griffiths <i>et al.</i> | | | 05/29/1996 |
| | AC13 | 6,040,430 | 03/21/2000 | Stewart | | | 12/26/1995 |
| | AD13 | 6,063,627 | 06/16/2000 | McVey <i>et al.</i> | | | 02/25/1998 |
| | AE13 | 6,066,778 | 05/23/2000 | Ginsburg, <i>et al.</i> | | | 11/06/1996 |
| | AF13 | 6,080,576 | 06/27/2000 | Zambrowicz, <i>et al.</i> | | | 04/08/1998 |
| | AG13 | 6,225,121 | 05/01/2001 | Savakis, C. <i>et al.</i> | | | 04/27/1998 |
| | AH13 | 6,262,341 | 07/17/2001 | Baszczynski <i>et al.</i> | | | 11/17/1998 |
| | AI13 | 6,271,436 | 08/07/2001 | Piedrahita <i>et al.</i> | | | 10/10/1997 |
| | AJ13 | 6,331,397 | 12/18/2001 | Schindelhauer <i>et al.</i> | | | 05/11/2000 |
| | AK13 | 6,361,972 | 03/26/2002 | Harrington <i>et al.</i> | | | 01/10/2000 |

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| | AL7 | WO 96/40722 | 12/19/1996 | WIPO | | | Yes No |
| | AM7 | WO 96/40724 | 12/19/1996 | WIPO | | | Yes No |
| | AN7 | WO 97/06265 | 02/20/1997 | WIPO | | | Yes No |
| | AO7 | WO 97/09436 | 03/13/1997 | WIPO | | | Yes No |
| | AP7 | WO 97/25446 | 07/17/1997 | WIPO | | | Yes No |

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

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| | AR | <u>83</u> | Ausubel, F.M., <i>et al.</i> , "Mutagenesis by the Polymerase Chain reaction," in <i>Current Protocols in Molecular Biology</i> , John Wiley & Sons, Inc., Boston, MA, pp. 8.5.1-8.5.9 (1995) |
| | AS | <u>83</u> | Ayres, E.K., <i>et al.</i> , "Precise Deletions in Large Bacterial Genomes by Vector-mediated Excision (VEX) The <i>trfA</i> Gene of Promiscuous Plasmid RK2 is Essential for Replication in Several Gram-negative Hosts," <i>J. Mol. Biol.</i> 230:174-185, Academic Press (1993) |
| | AT | <u>83</u> | Babineau, D., <i>et al.</i> , "The FLP Protein of the 2-micron Plasmid of Yeast," <i>J. Biol. Chem.</i> 260:12313-12391, American Society for Biochemistry and Molecular Biology, Inc. (1985) |

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| | AA14 | 6,365,377 | 04/02/2002 | Patten <i>et al.</i> | | | 03/03/2000 |
| | AB14 | 2002/0068290 A1 | 06/06/2002 | Yarovinsky | | | 05/31/2001 |
| | AC14 | 6,410,266 | 06/25/2002 | Harrington <i>et al.</i> | | | 01/07/2000 |
| | AD14 | 6,410,317 B1 | 06/25/2002 | Farmer | | | 07/14/2000 |
| | AE14 | 2002/0094574 A1 | 07/18/2002 | Hartley <i>et al.</i> | | | 05/16/2001 |
| | AF14 | 6,436,707 | 08/20/2002 | Zambrowicz <i>et al.</i> | | | 03/25/1999 |
| | AG14 | 2002/0172997 A1 | 11/21/2002 | Hartley <i>et al.</i> | | | 07/19/2001 |
| | AH14 | 2002/0182731 A1 | 12/05/2002 | Ji <i>et al.</i> | | | 01/25/2002 |
| | AI14 | 2003/0027289 A1 | 02/06/2003 | Farmer | | | 04/05/2002 |
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| | AL8 | WO 97/32481 | 09/12/1997 | WIPO | | | Yes No |
| | AM8 | WO 98/10086 | 03/12/1998 | WIPO | | | Yes No |
| | AN8 | WO 98/53056 | 11/26/1998 | WIPO | | | Yes X No |
| | AO8 | WO 99/10488 | 03/04/1999 | WIPO | | | Yes No |
| | AP8 | WO 99/21977 | 05/06/1999 | WIPO | | | Yes No |

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| | AR | <u>84</u> | Backman, K., <i>et al.</i> , "Use of Synchronous Site-Specific Recombination <i>In Vivo</i> to Regulate Gene Expression," <i>Bio/Technology</i> 2:1045-1049 (1984) |
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| | AT | <u>84</u> | Balakrishnan, R., <i>et al.</i> , "A gene cassette for adapting <i>Escherichia coli</i> strains as hosts for <i>att</i> -Int-mediated rearrangement and p_L expression vectors," <i>Gene</i> 138:101-104, Elsevier Science (January 1994) |

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| | AC15 | 2003/0064515 A1 | 04/03/2003 | Hartley <i>et al.</i> | | | 01/30/2002 |
| | AD15 | 2003/0068799 A1 | 04/10/2003 | Hartley <i>et al.</i> | | | 06/06/2002 |
| | AE15 | 2003/0077804 A1 | 04/24/2003 | Byrd <i>et al.</i> | | | 04/19/2002 |
| | AF15 | 2003/0124555 A1 | 07/03/2003 | Brasch <i>et al.</i> | | | 05/21/2002 |
| | AG15 | 2003/0157662 A1 | 08/21/2003 | Gerard <i>et al.</i> | | | 11/13/2002 |
| | AH15 | 2003/0175970 A1 | 09/18/2003 | Hartley <i>et al.</i> | | | 11/21/2002 |
| | AI15 | 2004/0053412 A1 | 03/18/2004 | Hartley <i>et al.</i> | | | 03/26/2003 |
| | AJ15 | 6,720,140 | 04/13/2004 | Hartley <i>et al.</i> | | | 02/04/2000 |
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| | AL9 | WO 99/25851 | 05/27/1999 | WIPO | | | Yes X No |
| | AM9 | WO 99/55851 | 11/04/1999 | WIPO | | | Yes No |
| | AN9 | WO 00/12687 | 03/09/2000 | WIPO | | | Yes No |
| | AO9 | EP 1 035 208 | 09/13/2000 | Europe | | | Yes No |
| | AP9 | WO 00/60091 | 10/12/2000 | WIPO | | | Yes No |

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| | AR | <u>85</u> | Barnes, G., and Rine, J., "Regulated expression of endonuclease <i>EcoRI</i> in <i>Saccharomyces cerevisiae</i> : Nuclear entry and biological consequences," <i>Proc. Natl. Acad. Sci. USA</i> 82: 1354-1358, National Academy of Sciences (1985) |
| | AS | <u>85</u> | Bauer, C.E., <i>et al.</i> , "Extent of Sequence Homology Required for Bacteriophage Lambda Site-specific Recombination," <i>J. Mol. Biol.</i> 181:187-197, Academic Press Inc. (1985) |
| | AT | <u>85</u> | Bayley, C.C., <i>et al.</i> , "Exchange of gene activity in transgenic plants catalyzed by the Cre-lox site specific recombination system," <i>Plant Mol. Biol.</i> 18:353-361, Dordrecht Kluwer Academic (1992) |

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| | AL10 | WO 01/05961 | 01/25/2001 | WIPO | | | Yes No |
| | AM10 | WO 01/07572 | 02/01/2001 | WIPO | | | Yes No |
| | AN10 | WO 01/62892 | 08/30/2001 | WIPO | | | Yes No |
| | AO10 | WO 02/05294 | 01/17/2002 | WIPO | | | Yes No |
| | AP10 | WO 02/08391 | 01/31/2002 | WIPO | | | Yes No |

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| | AR | <u>86</u> | Bernard, P., and Couturier, M., "Cell Killing by the F plasmid Ccdb Protein Involves Poisoning of DNA-topoisomerase II Complexes," <i>J. Mol. Biol.</i> 226:735-745, Academic Press, Inc. (1992) |
| | AS | <u>86</u> | Bernard, P., "Positive Selection of Recombinant DNA by CcdB," <i>BioTechniques</i> 21:320-323, Eaton Publishing Company (1996) |
| | AT | <u>86</u> | Bernard, P. <i>et al.</i> , "The F Plasmid CcdB Protein Induces Efficient ATP-dependent DNA Cleavage by Gyrase," <i>J. Mol. Biol.</i> 234:534-541, Academic Press, Inc. (1993) |

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| | FIRST NAMED INVENTOR Bennett <i>et al.</i> | |
| | FILING DATE July 18, 2003 | ART UNIT 1653 |
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| | AL11 | WO 03/25161 | 03/27/2003 | WIPO | | | Yes No |
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| | AT | <u>96</u> | CLONTECH, "Creator™: The Universal Platform for Analysis of Gene Function," <i>Powerpoint Presentation</i> , pp. 1-9, CLONTECH, (July 24, 2001), available at http://www.clontech.com/products/families/creator/popups/s1page1.html |

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| | FIRST NAMED INVENTOR Bennett <i>et al.</i> | |
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| | FIRST NAMED INVENTOR Bennett <i>et al.</i> | |
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| | FIRST NAMED INVENTOR Bennett <i>et al.</i> | |
| | FILING DATE July 18, 2003 | ART UNIT 1653 |
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| | AR | <u>118</u> | Institut Pasteur Websites Figure 1: http://www.pasteur.fr/recherche/unites/pmtg/integ/fig1.html (accessed 6/19/2003) |
| | AS | <u>118</u> | Institut Pasteur Websites Figure 2: http://www.pasteur.fr/recherche/unites/pmtg/integ/fig2.html (accessed 6/19/2003) |
| | AT | <u>118</u> | Institut Pasteur Websites Figure 3: http://www.pasteur.fr/recherche/unites/pmtg/integ/fig3.html (accessed 6/19/2003) |

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| | AT | <u>119</u> | Jayaram, M., "The <i>Int</i> Family of Site-specific Recombinases: Some thoughts on a General Reaction Mechanism," <i>J. Genet.</i> 67:29-36, Indian Academy of Sciences (1988) |

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| | AT | <u>120</u> | Kanaar, R., <i>et al.</i> , "Gin-Mediated Recombination of Catenated and Knotted DNA Substrates: Implications for the Mechanism of Interaction Between <i>Cis</i> -Acting Sites," <i>Cell</i> 58:147-159, Cell Press (1989) |

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| | AT | <u>121</u> | Kealey, J.T., <i>et al.</i> , "Production of Polyketide Natural Product in Nonpolyketide-producing Prokaryotic and Eukaryotic Hosts," <i>Proc. Natl. Acad. Sci. USA</i> 95:505-509, National Academy of Sciences (January 1998) |

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| | AR | <u>122</u> | Kholodenko, B.N., <i>et al.</i> , "Metabolic Design: How to Engineer a Living Cell to Desired Metabolite Concentrations and Fluxes," <i>Biotechnol. Bioengineer.</i> 59:239-247, John Wiley & Son (1998) |
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| | AS | <u>123</u> | Kitts, P.A., and Nash, H.A., "Bacteriophage Lambda Site-Specific Recombination Proceeds with a Defined Order of Strand Exchanges," <i>J. Mol. Biol.</i> 204:95-107, Academic Press, Inc. (1988) |
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| | FIRST NAMED INVENTOR Bennett <i>et al.</i> | |
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| | FIRST NAMED INVENTOR Bennett <i>et al.</i> | |
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| | FIRST NAMED INVENTOR Bennett <i>et al.</i> | |
| | FILING DATE July 18, 2003 | ART UNIT 1653 |

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| | AJ | | | | | | |
| | AK | | | | | | |

FOREIGN PATENT DOCUMENTS

| EXAMINER INITIAL | | DOCUMENT NUMBER | DATE | COUNTRY | CLASS | SUB-CLASS | TRANSLATION |
|---------------------|----|-----------------|------|---------|-------|-----------|-------------|
| | AL | | | | | | Yes No |
| | AM | | | | | | Yes No |
| | AN | | | | | | Yes No |
| | AO | | | | | | Yes No |
| | AP | | | | | | Yes No |

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

| | | | |
|--|----|------------|---|
| | AR | <u>180</u> | Zhu, X.D., <i>et al.</i> , "Homology requirements for ligation and strand exchange by the FLP recombinase," <i>J. Biol. Chem.</i> 270:11646-11653, American Society for Biochemistry and Molecular Biology (1995) |
| | AS | <u>180</u> | U.S. Patent Application No. 10/640,422, Cheo <i>et al.</i> , filed August 14, 2003 (NOT PUBLISHED) |
| | | | |

EXAMINER

DATE CONSIDERED

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.